Kansas Department of Health and Environment

Guidelines for Management of a Suspect Case of Smallpox in Acute Care Medical Settings in Kansas

Revised March 15, 2003
Updates available at http://www.kdhe.state.ks.us/han/bioterror.html

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We thank the New York City Department of Health and Mental Hygiene for their contribution to the development of ample portions of the format and content of this document.

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Since the events of September 11, 2001 and the subsequent intentional distribution of mail contaminated with anthrax there has been an acceleration of public health preparedness at the local, state, and federal levels with respect to the possible introduction of smallpox as a biological weapon. The Kansas Department of Health and Environment (KDHE) has developed these guidelines for hospitals and other acute care medical settings to use when evaluating a patient with "suspected smallpox".

These guidelines focus on the management of a "suspect" smallpox case occurring in the absence of an already recognized outbreak, that is, a case that may represent the index case of a bioterrorist event. Once there is one or more cases of laboratory-confirmed smallpox in the state, further specific guidance on patient management, contact investigation, and control activities will be provided by KDHE and the Centers for Disease Control and Prevention (CDC).[1]

I. Steps that all hospitals should consider to ensure preparedness in the event that a suspect smallpox case presents at their institution

KDHE recommends that all hospitals ensure their preparedness for the evaluation and management of a suspect smallpox case through the following steps:

A) Ensure that an effective emergency response (disaster) plan and infrastructure is in place, including but not limited to:

1) An active, functional emergency response (disaster) committee with representatives from hospital, medical and nursing administration; internal medicine, pediatrics, and infectious disease departments; infection control; microbiology; emergency medicine; intensive care; pharmacy; employee health; public affairs; operations; Management Information Systems; legal services; mental health; central supply; engineering; laundry; waste management; and hospital security.

2) Notification protocols to ensure that all relevant hospital staff and outside agencies are notified rapidly in the event of an emergency should be established ahead of time. This will require having 24-hour contact information for all key staff, including home telephone, pagers, cell phones and electronic mail (including mobile electronic mail accounts, when available) as well as a telephone tree system or emergency notification software to ensure the ability to rapidly contact staff to request that they report

[1] General guidance on the management of smallpox patients and outbreaks is already available through KDHE (http://www.kdhe.state.ks.us/han/bioterror.html) and CDC (www.bt.cdc.gov).

to duty. Twenty-four hour emergency contact information for key local and state agencies (e.g., KDHE, Kansas Division of Emergency Management, Local Health Department) should be included in the hospital's emergency response plan (see Appendix II).

3) A 24/7 communications network with back-up communication systems should be considered in the event that the routine network is disabled.

4) Each hospital should have at least one key staff member subscribing to the state Health Alert Network's PHIX notification system. More information can be found at HTTP://phix.kdhe.state.ks.us.

5) Regular educational training should be provided to all hospital staff regarding the hospital's emergency response plans, and each staff person's expected role and responsibilities.

6) The presence of an incident command system is recommended for most emergency response plans. An incident command system allows coordination of the emergency response along standardized functional responsibilities. The incident command system includes pre-designated roles, lines of authority and chains of communication, with at least one appropriate alternate/back-up person for each position. Job action sheets are prepared ahead of time outlining the roles and responsibilities for all emergency response positions. KDHE is planning to provide training in the near future for hospital officials on how to effectively use an incident command system.

B) As part of overall emergency response (disaster) planning, each hospital should develop a specific response plan for smallpox. This plan should be developed in conjunction with the KDHE's Bioterrorism Preparedness Program and the local health department. The plan should be tested and tabletop exercises and drills should be conducted to evaluate the hospital response to a suspect smallpox case.

C) Ensure that the emergency department and all primary care clinics have protocols in place to quickly identify patients presenting with significant fever and rash illness and to isolate them immediately pending clinical evaluation (see Section II for details).

D) Ensure that all pre-hospital transportation services (e.g., Emergency Medical Services) are aware of the need to notify the emergency department and/or clinic staff when transporting any patient with significant fever and rash illness so that the patient can be immediately placed in isolation on arrival.

E) When allowed by architectural and budget constraints, ensure that the emergency department has at least one airborne infection isolation room.

Airborne infection isolation rooms are defined as negative pressure isolation rooms with a minimum of 6-12 air exchanges per hour and direct exhaust to the outside which is located more than 25 feet from an air intake and from where people may pass (if air cannot be exhausted directly to the outside more than 25 feet from an air intake and from where people may pass, then air should be filtered through a HEPA filter. HEPA filters are tested with 0.3 micron particles, which are similar in size to that of a smallpox virion, which are 0.25 to 0.4 microns. These rooms should be tested monthly (and daily when in use) to verify negative airflow.

When an airborne infection isolation room is not a viable option, or in clinical areas (e.g., primary care clinics) that do not have airborne infection isolation rooms that meet the above criteria, an enclosed room(s) should be pre-identified for isolating a suspect patient as far apart as possible from other patients and staff pending clinical evaluation (e.g. a separate wing, or an examination room at the end of a hallway). In the emergency departments, the room designated for airborne infection isolation should ideally have a toilet and sink.

F) Emergency department, infection control and plant management/engineering staff need to understand the air flow characteristics of the emergency department, assess potential risks and determine the most effective strategies in their facility to minimize the likelihood of smallpox transmission, should a suspect case be identified. The majority of emergency departments do not recirculate air to other parts of the facility. If air does recirculate to other parts of the facility, infection control and plant management/engineering staff should know what areas of the hospital might potentially be affected as well as assess ahead of time the relative benefits and risks of shutting down the ventilation system, in response to a suspect smallpox case-patient. (*Hospitals may consider retrofitting the HVAC systems in these areas with HEPA filtration units and/or installing UVGI units.*)

G) Maintain an up-to-date list of all isolation rooms (as defined in Section I.E) in the in-patient facility and ensure that all airborne infection isolation rooms are evaluated monthly (and daily when in use) to verify negative airflow characteristics. Pre-identify specific floor(s) or unit(s) with isolation rooms that would be used to admit a suspect or confirmed smallpox case(s). Consideration should be given ahead of time regarding the optimal route for transporting the suspect case(s) from the emergency department or clinic area to this pre-designated floor/unit.

H) Maintain enhanced awareness among all clinical care staff regarding the potential for bioterrorism and the key diagnostic clues to potential bioterrorist agents, including smallpox, and conduct training activities on at least an annual basis. All medical and

nursing staff should receive educational training on the clinical presentation of smallpox and the differential diagnosis of vesicular and pustular rashes. Place copies of the CDC's poster on "Evaluating Patients for Smallpox – Acute, Generalized Vesicular and Pustular Rash Illness Protocol" in the medical areas of the emergency department and all primary care clinics.[2] **All healthcare providers should know to report immediately any suspect smallpox case to KDHE's 24 hour contact number (1-877-427-7317).**

I) Provide digital pictures to KDHE consultants for timely evaluation of suspect smallpox cases. Digital photographs can be taken of the suspect patient's lesions and the image sent via electronic mail to KDHE physicians. KDHE physicians will consult with other experts (including CDC) to assist in the rapid evaluation of the patient for smallpox, as well as other cutaneous manifestations of diseases of potential bioterrorist or public health importance (e.g., cutaneous anthrax, measles, etc.). KDHE field staff will be immediately deployed to any hospital reporting a patient with a moderate risk or high risk of smallpox[3]. Hospitals (particularly those with large emergency rooms) should consider acquiring one digital camera for key personnel (e.g., emergency department staff) and train them in its proper use (including downloading the images for electronic mail transmission) to facilitate rapid consultation with KDHE. Electronic mail addresses to send digital pictures for evaluation will be provided by calling the KDHE 24 hour contact number. **KDHE field staff are equipped with digital cameras,** and they can be rapidly deployed to any hospital in the state to assist in obtaining digital pictures and transmitting them to KDHE. The activation of these employees will be decided by the KDHE medical epidemiologists after notification of the presence of a possible case of smallpox.

J) Consider pre-designating teams of healthcare providers (including adult and pediatric medical staff, nursing, emergency medicine, infectious disease, dermatology, laboratorians, and housekeeping) that would be mobilized to care for any suspect or confirmed smallpox case. These pre-identified staff should preferably be persons who were vaccinated against smallpox in the last three to five years. Some health care and public health workers have been immunized in 2003, as a part of the national smallpox preparedness campaign. In the absence of the recently vaccinated staff, the hospital should identify those that have been vaccinated at least once previously. The smallpox vaccine was routinely given in the United States until about 1980, and was administered in the military until 1990.While previous vaccination may not confer complete protection, staff with one or more smallpox vaccinations in the past may have some protection against severe illness and death.

Previously vaccinated staff would still need to use appropriate personal protective equipment and strictly adhere to airborne and contact precautions during all patient care activities. These staff should receive regular training on airborne and contact precautions and on the use of Personal Protective Equipment, including respiratory

[2] Details on how to obtain copies of this CDC poster are included in Section II.C
[3] See definitions below, section II.C and Appendix I

Immediate Actions Required from Health Care Providers

In the presence of a suspect case of smallpox, KDHE is instructing hospital staff and other health care providers dealing with the case to implement immediately the following three critical action items:

1) Isolate the patient.

2) Collect contact information on individuals who were in close contact with the patient from the time the patient arrived at the facility to the time the patient was isolated.

3) Immediately contact the KDHE hotline (1-877-427-7317).

masks (N-95 or higher). Fit testing for respiratory masks should also be performed, as recommended by the manufacturer.

K) Assure that the hospital smallpox response plan is carefully reviewed at least twice a year, and practiced at least yearly.

L) Ensure that laboratorians are trained in the proper handling of routine clinical specimens and understand that the risk of smallpox infection due to contact with samples from a suspect case is low when handled appropriately.

II. Initial Evaluation of Patients with an Acute, Generalized Vesicular or Pustular Rash and Criteria for Notification of KDHE Based on the Likelihood of Smallpox

All hospitals and clinics should have policies in place to ensure the identification of any patient presenting for evaluation in an emergency department or other primary care clinical setting with a significant fever and an acute, generalized, vesicular or pustular rash. The patient should be immediately placed in isolation with airborne and contact precautions., The infection control staff should be notified immediately while the patient awaits further clinical evaluation.[4]

A) Recognition of a Suspected Smallpox Case

1) Signage (bi- or multilingual depending on the hospital's patient population) should be placed at the walk-in entrance to the emergency department and primary care clinics stating that any patient with fever and rash illness immediately inform security or triage staff.

[4] The measures described here are similar to those that should be applied for suspect cases of other airborne diseases, such as tuberculosis, varicella, or measles.

2) Triage, receptionist and all primary care staff should be trained to be alert for patients with a significant febrile rash illnesses, and immediately notify the appropriate nursing or medical staff. The patient's placement in the room pre-designated for airborne isolation (see Sections I.E. for details on the criteria for airborne infection isolation rooms) should be expedited**.**

3) All ambulance or pre-hospital transport services should be alert to the need to pre-notify the emergency department staff if transporting a patient with a significant fever and rash illness so that the patient can be immediately placed in isolation upon arrival. Hospitals are encouraged to work with Emergency Medical Systems operating in their areas to alert them about the importance of this procedure.

B) Isolation of a Suspected Smallpox Case Pending the Initial Clinical Evaluation by Emergency Department or Clinic Staff

1) Contact precautions should be used by staff at all times.

2) **A surgical mask should immediately be placed on patients presenting with a significant fever and a rash illness. They should be escorted directly to the room pre-designated for airborne isolation**. If suspect patients are initially seen in clinical areas (e.g., primary care clinics) that do not have pre-designated isolation rooms as defined in Section I.E., a surgical mask should be placed on the patient, and he/she should be isolated from other patients and staff as best as possible pending clinical evaluation (e.g., an enclosed examination room separated from other patients at the end of a hallway).

3) Further details on isolation precautions that should be taken for the care of suspected smallpox cases are outlined in Section IV. These precautions may be discontinued once the medical evaluation has ruled out smallpox or other potentially communicable diseases that are spread by airborne transmission.

C) Clinical Assessment of a Suspect Smallpox Case

In the absence of a confirmed case of smallpox anywhere in the world, cases of suspect smallpox are likely to be atypical or severe manifestations of chickenpox. Therefore a key feature in the differential diagnosis is to rule in or rule out chickenpox infection.
The clinical assessment of the risk of smallpox should use the CDC criteria for determining whether the patient is at low, moderate or high risk for smallpox, as summarized in Appendix I. The full protocol with color photographs is available as a poster ("Evaluating Patients for Smallpox – Acute, Generalized Vesicular and Pustular Rash Illness Protocol, version 1.0 31 January, 2002") and copies of this poster can be obtained by calling the KDHE Bioterrorism Preparedness Program

during business hours (785-296-8605), sending an email request to bt@kdhe.state.ks.us , or through the CDC website at http://www.bt.cdc.gov/agent/smallpox/smallpox-images/index.asp.

1) For **low risk patients**, as defined on the CDC poster "Evaluating Patients for Smallpox," and in Appendix I of this Guideline (especially if chickenpox or disseminated herpes zoster is the likely diagnosis based on history and physical examination), varicella laboratory testing is optional, and the patient should be kept under airborne and contact isolation per the hospital's varicella protocol. For patients determined to be at low risk for smallpox, but for whom the diagnosis is uncertain, laboratory testing for varicella zoster virus antigen (using rapid DFA or PCR tests) and/or other conditions should be considered as indicated clinically. **It is NOT necessary to report the case to KDHE, unless a consultation is needed or rapid varicella antigen testing is needed.**

2) For **moderate risk patients**, as defined on the CDC poster "Evaluating Patients for Smallpox" and in Appendix I of this Guideline, KDHE should be contacted immediately (1-877-427-7317). In addition, an infectious disease or dermatology consult should be arranged, as well as rapid testing for varicella (DFA or PCR testing for varicella antigen) if available, and for other diseases as clinically indicated. **KDHE should be contacted immediately, and will assist in determining the likelihood of smallpox and arrange for rapid diagnostic testing for varicella antigen, if needed.**

3) For **high risk patients**, as defined on the CDC poster "Evaluating Patients for Smallpox" and in Appendix I of this Guideline, **KDHE should be contacted immediately**. KDHE will provide rapid medical, epidemiology, and laboratory consultation to the hospital to assist with the diagnosis of these patients and their management.

III. Consultation with KDHE

A) Contact Information for KDHE

KDHE should be consulted immediately for any patient deemed to be at **moderate** or **high risk** for smallpox**. KDHE staff are available for consultations on a 24 hour, 7 day per week basis by calling 1-877-427-7317.**

To report a suspect case of smallpox to KDHE: Call the Epidemiologic Services Section at 1-877-427-7317, 24 hours a day.
(If there are difficulties reaching the KDHE epidemiologist, please contact the Kansas Division of Emergency Management at 1-800-905-7521)

For questions about preparedness plans, exercises, or to order educational and information material (e.g., posters), call the KDHE Bioterrorism Preparedness Program during regular business hours at (785) 296-8605.

B) KDHE Initial Triage of Calls Regarding Suspect Smallpox Cases

KDHE has medical epidemiologists that are available on a 24-hour, 7 day a week basis to assist providers in evaluating suspect smallpox cases, in consultation with CDC. In addition, KDHE has rapid varicella DFA antigen testing available at the State Health and Environmental Laboratory to assist in differentiating chickenpox or disseminated herpes zoster from smallpox. Details on specimen collection and submission can be found in Annex III. If a specimen from a patient with suspect smallpox tests negative for chickenpox, the specimen will then be tested for smallpox. Currently, laboratory tests for smallpox are only available at the CDC.[5] Therefore, KDHE will arrange for immediate transportation of the specimen to the CDC. Test results should be available within 8 hours of the specimen's arrival in Atlanta to guide further clinical and public health management of the patient.

KDHE is also in the process of setting up a *network of clinical specialists* available to assist in the diagnosis and management of patients with suspect bioterrorism-related diseases, such as smallpox. Specialists in this network will be available for consultation through KDHE, as needed.

The KDHE medical epidemiologist will initially discuss the case by telephone with the reporting physician to determine the likelihood of smallpox. Digital photographic images may be obtained by the KDHE field staff or by the hospital staff and sent by electronic mail to the KDHE medical epidemiologist or consultant. A rapid determination will be made on whether the patient is at moderate or high risk for smallpox.

D) Notification of other City, State and Federal Agencies:

KDHE will notify their epidemiologic counterparts at the Local Health Department and at CDC regarding all suspect cases deemed to be at moderate or high risk for smallpox. KDHE will maintain communications with the State Division of Emergency Management and the Regional Office of the US Department of Health and Human Services in Kansas City throughout the event. The State Division of Emergency Management will notify all other appropriate state and federal agencies, as indicated. For cases classified as low risk for smallpox only the local health department of the affected area will be notified.

IV. Management of the Patient and Infection Control Practices Pending KDHE Evaluation and/or Laboratory Test Results for Smallpox

KDHE advises hospitals to take the following steps for managing suspect moderate or high risk patients (as defined on the CDC poster "Evaluating Patients for Smallpox" and

[5] PCR tests for smallpox may become available at the KDHE laboratory once CDC provides the required reagents.

in Appendix I of this Guideline) while awaiting further recommendations from the KDHE epidemiologic team or laboratory test results.

A. When a diagnosis of smallpox is suspected or confirmed, steps must be taken to protect other patients, staff, and visitors from smallpox infection. The patient should be kept in a room pre-designated for isolation (as defined in Section I.E.). Suspected or confirmed smallpox patients should be kept in their rooms except for medically essential procedures that necessitate transport to other hospital locations. ***Transfer to another hospital should be considered only if medically necessary to protect the life of the patient*** (e.g., need for intensive care in a hospital that does not have an ICU available). To minimize the potential for contamination when transported outside of their isolation rooms, a surgical mask should be placed on the suspected or confirmed smallpox patient(s), a sheet should be used to cover their skin as much as possible, and efforts should be made to minimize patient movement and manipulation of the patient's linens to protect against aerosolization of any potentially infectious material. The route for moving the patient should be cleared of all people not involved in the transfer. All staff should continue to wear a gown, gloves, and a mask or respirator (N-95 or above) even when the patient is covered and wearing the surgical mask.

B. Infection control personnel in the hospital should be immediately notified regarding the suspect case. If not already involved, consultations should be requested from dermatology and infectious disease specialists, if available. If such consultations are not available, a request can be made to KDHE to consult with one of the clinical specialists in the bioterrorism clinical network (see section III.D).

C. A standardized isolation sign noting the need for airborne and contact precautions should be displayed outside the patient's room, and an isolation cart should be placed outside the door.

D. The door to the patient's room should be kept closed (self-closing doors are preferable).

E. All personal protective equipment (e.g., gowns, gloves, and masks) should be stocked outside the door to the patient's room. Persons leaving the room should dispose of their protective clothing and equipment and wash their hands in a pre-designated area right outside the isolation room.

F. The number of persons who enter the patient's room should be reduced to the minimum necessary, as well as the traffic in and out. No visitors should be allowed, with some limited exceptions for immediate family members who have already had contact with the patient prior to hospitalization.

G. Preferably, no staff person without at least one prior vaccination for smallpox should be allowed in the patient's room (see section I.I. on pre-designated teams of health care providers).

H. All hospital staff (including transport personnel) and visitors must don contact and airborne personal protection equipment prior to entering a suspected or confirmed smallpox patient's room [i.e., disposable gloves and gowns and an N-95 or higher respiratory mask] regardless of their prior smallpox vaccination status. All staff should have undergone fit-testing for respiratory masks.

I. After use, all personal protective equipment (e.g., gowns, gloves, and masks) should be placed into a plastic biohazard bag and left in the patient's room or in the anteroom, if available.

All staff and visitors entering the room should be instructed in the meaning of contact, airborne and standard precautions.

After the diagnosis of smallpox is confirmed, care for the patient cannot be provided in the same environment where other patients are admitted. The smallpox patient(s) shall be placed in an airborne isolation room, or (if that is not an option) cared for in a separate part of the building that has restricted access, an isolated ventilation system, and is physically distinct from other patient care areas (e.g., a separate wing or floor). Hospital evacuation plans should be enacted, if necessary, and other patients should be moved to assure adequate isolation of the smallpox patient.

L. Specific Infection Control Recommendations:

1) Dedicated equipment (e.g., blood pressure cuffs and stethoscopes) should be left in the room when possible. No personal equipment (e.g., stethoscopes) should be used on the suspect patient and then taken out of the room for use on other patients.
2) Use disposable items whenever possible. Arrange to have food brought into the room in disposable containers.
3) Dispose of all non-sharps waste in biohazard bags and have these bags autoclaved before disposal or transport for incineration.
4) Place all laundry and linens (e.g., bedding, towels) in water-soluble biohazard bags that can be used to transport laundry. The bag (with laundry inside) should be placed directly in the laundry machine without opening the bag to protect against aerosolization of any potentially infectious material. If water-soluble bags are not available, the items may be transported to the laundry in biohazard bags, then laundered using hot water (71 ºC) and bleach according to the standard proportions recommended by the manufacturer. The contaminated clothing should be wetted before sorting by laundry personnel as this should help prevent the aerosolization of contaminated particles during

sorting. Housekeeping and laundry workers should always wear gloves when handling the laundry or laundry bag.[6]

V. Management of the Emergency Department or Clinic Area where the Suspect Patient at Moderate or High Risk for Smallpox was Initially Seen Prior to Isolation, Pending KDHE Evaluation and/or Laboratory Test Results

The following guidelines apply to the emergency department or clinic area where the moderate to high risk patient (as defined on the CDC poster "Evaluating Patients for Smallpox" and in Appendix I of this Guideline) was initially seen and may have spent time prior to being placed in an airborne infection isolation room, pending the diagnosis. All hospital emergency departments and primary care clinics are expected to have triage protocols in place to rapidly identify and effectively isolate any patient with a significant fever and rash illness in order to minimize the number of persons potentially exposed in the waiting area.

A) Procedures for Laboratory Testing

If the patient is located in Kansas and testing is deemed to be necessary, the specimen(s) will be moved to the Kansas Health and Environment Laboratory (KHEL), using rapid transportation methods provided through the Kansas Highway Patrol. Upon delivery of the specimen(s) to the KHEL, tests will be performed for presence of varicella-zoster virus.[7] Local health departments and hospitals will be instructed to wait until the test results are available and communicated to them by the KDHE Epidemiology Services Section staff. Any calls before the test is completed will be referred to KDHE's Bureau of Epidemiology and Disease Prevention.

It is envisioned that the KHEL testing will be completed in less than two hours after arrival at the laboratory. The Bureau of Epidemiology and Disease Prevention will inform of the test results, whether positive or negative, the submitting hospitals and all parties that had been notified by the bureau of the ongoing crisis (see above, *Inter-agency Notification and Coordination*). Much of this information will be distributed using the Public Health Information Exchange (PHIX) system (see Appendix B of the Crisis Emergency Risk Communication Plan [Appendix 3]).

If further testing is needed at the CDC, the KDEM will provide air transportation for the specimen. The KHEL will coordinate directly with KDEM for transportation and with CDC for packaging (if necessary) and provide one person

[6] Since the laboratory test results for a moderate to high risk patient will likely be available within 24-48 hours, hospitals may want to consider keeping all linens and other patient laundry in the patient's isolation room until smallpox has been ruled out. Once smallpox is confirmed by CDC, laundry should only be handled by vaccinated personnel. Laundry workers will be prioritized for vaccination once smallpox is confirmed.

[7] Additional and more specific testing will be forthcoming upon being approved by the FDA and the CDC.

to escort the specimen(s) to Atlanta. It is anticipated that diagnostic testing for variola will take up to 24 hours. If variola is not found, the alert status will be lowered, and the attending physician will resume primary management responsibility for the patient.

B) Currently, the case definitions and classification are as follows:
(After smallpox is confirmed, the case definitions for confirmed, probable, and suspect cases recommended by CDC at that time will be adopted.)

Clinical Case Definition - An illness with acute onset of fever >101º F followed by a rash characterized by vesicles or firm pustules in the same stage of development without other apparent cause.

Laboratory Criteria for Confirmation (to be conducted in Level C or D laboratories only):

1. Isolation of smallpox (variola) virus from a clinical specimen (Level D laboratory only), or
2. Polymerase chain reaction (PCR) identification of variola DNA in a clinical specimen, or
3. Negative stain electron microscopy (EM) identification of variola virus in a clinical specimen

Confirmed: a case of smallpox that is laboratory confirmed OR a case that meets the clinical case definition that is epidemiologically linked to a laboratory-confirmed case.

Probable: A case that meets the clinical case definition, OR a case that has an atypical presentation that is epidemiologically linked to a confirmed case of smallpox. Atypical presentations are: a) hemorrhagic type, b) flat type and c) variola sine eruption (this was added recently after discussion with smallpox experts; there is a qualifier stating this is rare and epidemiological significance is considered to be limited).

Suspect case: A case with a febrile rash illness with fever preceding development of a rash by 1-4 days.

It should be noted that after the appearance of confirmed smallpox cases, subsequent cases will not require a laboratory confirmation, as long as they meet the clinical criteria for smallpox. More details on laboratory and clinical diagnostic criteria can be found in Guide A of the CDC's *Smallpox Response Plan and Guidelines*, *version 3.*

C) Tracking and Management of Potential Contacts

1) The usual mechanism of spread of smallpox is droplet transmission (with larger particles falling out of the air quickly). Spread beyond 6 feet from the

patient is less likely, and unless the patient is coughing (oropharyngeal lesions are always present), aerosolization is also unlikely. **For purposes of tracking, "potential contacts" are defined as persons who were in close proximity (i.e., within 6 feet) to the suspect patient** (if this can be determined by emergency department or clinic staff), as long as the suspect patient did not have a significant cough. If the suspect patient has significant cough or it is not feasible to determine which persons were in close proximity contact, and the patient was not expeditiously triaged, all persons in the same room (i.e., waiting room) as the patient should be considered potential contacts.

2) Infection control or other properly instructed, and preferably vaccinated, hospital staff should track the names, job duty (for staff), home address, and all contact numbers (including home and work telephone, cellular phone, and beepers) for all hospital and ambulance staff, visitors and others who entered the patient's room or had potential contact with the patient from the moment he/she entered the hospital.

3) For low risk cases, no further action is recommended while waiting for the laboratory test results (if ordered), and potential contacts can be released after their contact information is collected.

4) For moderate to high risk cases, KDHE and local health department staff will immediately interview and counsel all potential contacts in the hospital, as well as provide educational materials (e.g., fact sheets) and a 24-hour telephone hotline number for all contacts to use in case they have additional questions or concerns after leaving the hospital.[8] All visitors and other patients in the emergency department/clinic who had potential contact with the suspect moderate or high risk patient should ideally be held in a separate room until interviewed by local or state public health staff which should begin within the hour of notification. These persons will also be counseled on:

    - their potential exposure and the likelihood of the suspect case being confirmed as smallpox;
    - the risk of their being infected with smallpox given the type and length of exposure that they had to the suspect patient (with consideration of whether the suspect case patient has significant cough symptoms);
    - the expected time when laboratory test results on the patient will be available from the CDC and how they will be notified of the results;
    - the consequences of a confirmed diagnosis (i.e., that if smallpox is confirmed, public health staff and/or the hospital would be

[8] If smallpox is confirmed, public health (i.e., KDHE and local health department) staff will also be responsible for tracking the patient's household and other close contacts outside the hospital.

contacting them within the next 24 hours to ensure that they immediately receive smallpox vaccine) and the fact that they would not be infectious to their household and close contacts immediately after exposure, even if the suspect case did have smallpox (i.e., that they can go home while awaiting laboratory test results and do not need to be quarantined as persons exposed to smallpox would not be considered infectious until they are symptomatic, which will be at least 7 days [usually about 10] after their contact with the index patient).

- the impact of exposure on their medical condition. Many staff, family, and all waiting patients will have concerns about their own unique health status. Collecting these individuals in one place presents a unique opportunity to allay fears and guide them in their health care needs.

5) Public health staff should be notified of any patient or visitor who had "potential contact" with the suspect moderate or high risk patient before they were placed in effective isolation and for whom there is concern that it may be difficult to locate these persons after they leave the hospital (e.g., homeless). If deemed necessary, public health staff will attempt to make arrangements to house these persons for an appropriate period of time to ensure the ability to locate and vaccinate the individual(s) in the event that smallpox is confirmed.

D) Decision on Hospital Quarantine or Temporary "Termination of Services"

The rationale and background justification (both from public health and legal perspectives) for the use of isolation of patients and quarantine of exposed individuals can be found in Guide C of CDC's *Smallpox Response Plan and Guidelines V.3*. State law K.S.A. 65-128 and regulation K.A.R. 28-1-2 et. seq. authorize the local health officer or Secretary of Health and Environment to order and enforce isolation and quarantine of persons afflicted with or exposed to infectious or contagious disease.

Individuals infected with smallpox typically become infectious only after onset of fever. Therefore, widespread, strict quarantine of exposed, asymptomatic individuals or of entire communities is not very helpful to contain the spread of the disease. *Large-scale quarantine* (where entire communities, cities, or states are cordoned off) has little or no place in the control of smallpox, and it is not part of the Kansas Smallpox Response Plan.

The following isolation and quarantine actions are recommended immediately after the recognition of a suspect case of smallpox in a health care facility.

1. If the suspect case is rapidly and effectively triaged and isolated on arrival to the emergency department or clinic (as described in Section II), there is no need to quarantine the hospital, emergency department, or clinic area or to consider

termination of medical services. There are only limited situations under which an emergency department or clinic should be quarantined or patient services be terminated due to concerns about the potential for airborne transmission from a patient with suspected smallpox. The only circumstances under which these actions might be considered would be (a) if the patient could not be effectively isolated for some reason, (b) the patient had a significant cough and was not recognized immediately and spent time in the waiting room where aerosolization may have occurred, or (c) if the emergency department/clinic had been disrupted (e.g., by multiple patients, or by panic among patients, families and staff) to such an extent that the emergency department/clinic could no longer function to provide patient care.

2. Nosocomial outbreaks of smallpox were occasionally reported in the past, with transmission to patients housed on floors far removed from the index case(s). However, there have since been marked improvements in the environmental safeguards in most of today's hospitals, given the infection control measures taken for tuberculosis and other communicable diseases. If a hospital facility does not have appropriate and modern respiratory isolation facilities, it should have a plan to isolate and manage the patient in accordance with Section IV, above Accordingly, it would be extremely unlikely for there to be any risk of smallpox transmission to staff, patients or visitors who did not have direct contact with the suspect patient (e.g., in areas of the hospital where the suspect patient did not spend <u>any</u> time), especially if the suspect patient is rapidly placed in an appropriate airborne infection isolation room. Therefore, <u>it should not be necessary to consider quarantine of the entire hospital building, or termination of all acute care services</u> while awaiting KDHE evaluation or laboratory test results for moderate to high risk smallpox cases.

Legally sanctioned and enforceable quarantine can only be decided by public health officials.[9] The decision to terminate services or lock down the emergency department or the whole hospital for reasons related to smallpox should be done by senior hospital administrative staff, in consultation with public health officials**.** To avoid exposure to liability, hospital administrators are strongly encouraged to consult with their legal counsel on the conditions under which locking down the hospital and restricting the movement of individuals who were in the facility when the suspect smallpox patient was admitted could be considered legal in the absence of an order from a public health authority. **It is strongly recommended that KDHE be involved in any decision regarding termination of services or hospital lock down.** Please call the epidemiologist on call at 1-877-427-7317.

<u>E) Sanitization of Emergency Department or Clinic Area</u>

All equipment and surfaces in the emergency department or clinic that may potentially have been in contact with the suspect patient (including in the waiting

[9] K.A.R. 28-1-5

room and any other rooms in which the patient was placed prior to moving to the isolation room) should be sanitized with standard hospital disinfectants (e.g., hypochlorite or quaternary ammonium compounds*)*, especially in any areas where a suspect patient has been coughing. Housekeeping staff, regardless of their prior smallpox vaccination status, should don appropriate personal protective equipment [i.e., disposable gloves and gowns and an N-95 or higher respiratory mask] while cleaning the area. These staff should have undergone fit-testing for respiratory masks[10]

VI. Additional Recommendations for the Hospital Administration to Ensure Effective Operation of the Hospital While Awaiting Laboratory Confirmation

A. Activation of the hospital's Emergency Preparedness (disaster) Plan: The decision whether to activate the hospital's emergency response (disaster) plan should be made based on the individual circumstances of the event. However, for a suspect patient thought to be at **moderate** to **high risk** for smallpox or if media attention or staff/patient/visitor's concerns are high enough so that the hospital is even potentially at risk for being unable to function normally, the Emergency Preparedness (disaster) Plan should be activated, including the hospital's Emergency Operations Center and Incident Command System. The Plan should ensure that the internal notification procedures and contact lists include all essential staff that might be needed in the event of a smallpox emergency (*e.g., infection control, infectious diseases, dermatology)* as well as emergency contact information for all key local and state agencies.

B. Communication Issues:

- Internal: The hospital administration and/or emergency response (disaster) committee should ensure that a mechanism and plan is in place for frequent communication with all hospital staff to address the likely concerns that they may have about the risk of smallpox in the institution and to provide timely updates on the situation, as new information becomes available. Mechanisms may include broadcast email, frequent meetings for each hospital shift, internal websites, etc. KDHE and the local health department will work closely with the hospital staff to develop educational materials and fact sheets, as well as provide speakers for internal briefings, if needed.

    - NOTE: **In the event of a suspect case that is being preliminarily worked up, it is strongly recommended that all clinical care staff be advised to minimize discussion of the suspected smallpox diagnosis in open areas where others may overhear and misinterpret the situation.** This will avoid unnecessary panic or a leak to the media for a case that may quickly be determined NOT to be smallpox.

[10] Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, MMWR 1994; 43 (R-13): page 72

- External: Although in general it is not necessary (nor recommended) that the media or the public be informed of the existence of a suspect case of smallpox while awaiting for laboratory confirmation, it is probable that this information may spread quickly. In this case, it is essential that a coordinated communication strategy be developed between the hospital public affairs staff and the local and state response agencies. KDHE and the local health department will provide the news media with the medical, epidemiologic, and infection control details relevant to the event, as needed. The KDHE Office of Public Information will work closely with the hospital staff if a public statement or press conference is needed while awaiting laboratory test results, to ensure consistent messages about the likelihood of smallpox and the steps being taken by the hospital and government agencies to determine the diagnosis, as well as any contingency plans being put into place, if indicated. Informational and educational material for both health care professionals and the public will be available through KDHE.

Telephone contact information for the KDHE Office of Public Information is as follows:

During business hours: Call 785-296-5795;
After hours, call the epidemiologist on call at 1-877-427-7317.

C. Security Issues: Ensure sufficient security is present to implement isolation and to respond to any potential disruptions that may occur due to the concerns about smallpox (e.g., significant media attention). If assistance is needed, the request should be directed to local law enforcement agencies and the local Emergency Management coordinator.

Security plans should include:

1) Ability to minimize points of access and egress to the physical plant.

2) A rapid identification process for hospital staff and local, state and federal emergency workers

3) An external vehicular "flow of traffic" prioritizing emergency vehicle access, supply delivery needs and law enforcement access

4) A method for routing persons other than patients to and from the facility

5) A triage protocol to route additional patients that may have smallpox based on fever and rash symptoms for immediate clinical evaluation to an appropriate, pre-designated site with sufficient airborne infection isolation rooms

6) Ensuring that appropriate protective equipment is provided to security staff, when indicated

D. Preparation for Facility-wide Vaccination: The section of the Emergency Preparedness Plan that deals with patients with suspected smallpox, in addition to the above, should ensure that smallpox vaccination can be offered to the hospital staff within 4 days of possible contact with the suspect patient.
Vaccination planning should include:

1. Ability to record contacts with the patient. Many times a "catastrophic" patient generates so much anxiety that organization and internal records are neglected. In this type of case, delay may decrease the maximum prophylactic value of the smallpox vaccination. Vaccination should occur within 3 or 4 days of exposure to minimize morbidity resulting from the contact.

2. Facilities to handle and control the numbers of staff to be vaccinated. Additionally, security of the site and the vaccine must be considered. It would be expected that large numbers of anxious members of the staff or public may be aggressively seeking vaccination.

3. Pre-identified staff to work in a vaccination effort. The facility should identify previously vaccinated personnel in enough numbers to ensure redundancy. Recently vaccinated workers would be preferable to those vaccinated in the distant past or those that have never been vaccinated.

4. Pre-identified sources to request the vaccine that include phone numbers for 24 hours a day and 7 days a week. KDHE procedures specify that the request come to KDHE via the most accessible method. The Epidemiology Hot-line is preferable, 1-877-427-7317. Requesting individuals should represent the facility and have advice and assistance from an infectious disease specialist who has been coordinating with KDHE.

Appendix I: Guidelines for Assessing Vesicular and Pustular Rashes

(Adapted from the CDC's Poster or "Evaluating Patients for Smallpox" version 1.0, January 31, 2002)

The following risk assessment should be considered when evaluating a patient with a vesicular or pustular rash to determine the likelihood of smallpox:

High Risk of Smallpox - All 3 of the following criteria must be present:

a) Febrile prodrome – Occurring 1-4 days before rash onset with fever ≥ 101 ^{o}F and at least one of the following: prostration, headache, backache, chills, vomiting or severe abdominal pain,

and

b) Classic smallpox lesions – Deep-seated, firm/hard, round well-circumscribed vesicles or pustules; as they evolve, lesions may become umbilicated or confluent,

and

c) Lesions in same stage of development – On any one part of the body (*e.g., the face or arm)* all the lesions are in the same stage of development (*i.e., all lesions are vesicles or all are pustules)*

Moderate Risk of Smallpox:

a) Febrile prodrome – Occurring 1-4 days before rash onset with fever ≥ 101 ^{o}F and at least one of the following: prostration, headache, backache, chills, vomiting or severe abdominal pain, **and either**

1-Classic smallpox lesions – Deep-seated, firm/hard, round well-circumscribed vesicles or pustules; as they evolve, lesions may become umbilicated or confluent,

or

2- Lesions in same stage of development – On any one part of the body (*e.g., the face or arm)* all the lesions are in the same stage of development (*i.e., all lesions are vesicles or all are pustules)*

OR

Febrile prodrome – Occurring 1-4 days before rash onset with fever ≥ 101 ^{o}F and at least one of the following: prostration, headache, backache, chills, vomiting or severe abdominal pain, **and FOUR or more of the following MINOR criteria:**

1) Centrifugal distribution: greatest distribution of lesions on the face and distal extremities
2) Initial lesions occur on the oral mucosa/palate, face or forearm
3) Patient appears toxic or moribund
4) Lesions exhibit a slow evolution – evolving from macules to papules and then to pustules over days (each stage lasts 1-2 days)
5) Lesions on the palms and soles

Low Risk of Smallpox:
a) No febrile prodrome, OR

b) Febrile prodrome – Occurring 1-4 days before rash onset with fever ≥ 101 ^{o}F and at least one of the following: prostration, headache, backache, chills, vomiting or severe abdominal pain, but **LESS THAN FOUR of the following MINOR criteria:**

1) Centrifugal distribution: greatest distribution of lesions on the face and distal extremities
2) Initial lesions occur on the oral mucosa/palate, face or forearm
3) Patient appears toxic or moribund
4) Lesions exhibit a slow evolution – evolving from macules to papules and then to pustules over days (each stage lasts 1-2 days)
5) Lesions on the palms and soles

Differentiation of Chickenpox from Smallpox

Chickenpox (varicella) is the most likely condition to be confused with smallpox. In chickenpox, the following findings on history and physical examination are usually found:

a) No or mild prodrome
b) Lesions are superficial vesicles ("dewdrops on a rose petal")
c) Lesions appear in crops; On any one part of the body, there are lesions in different stages (*papules, vesicles, pustules, crusted lesions)*
d) Centripetal distribution: greatest concentration of the lesions on the trunk, fewest lesions on the distal extremities. May involve the face and scalp. Occasionally, the entire body is equally affected
e) First lesions appear on the face or trunk
f) Patients are rarely toxic or moribund
g) Lesions progress through a rapid evolution from macules to papules to vesicles to crusted lesions (< 24 hours)
h) Palms and soles rarely involved
i) Patient lacks reliable history of either varicella infection or vaccination
j) 50-80% of patients recall a recent exposure to chickenpox or shingles within the 10-21 days before the onset of their rash

The full protocol with color photographs of smallpox and varicella skin lesions is available as a poster ("Evaluating Patients for Smallpox – Acute, Generalized Vesicular and Pustular Rash Illness Protocol"). Copies of this poster can be obtained by calling the KDHE Bioterrorism Preparedness Program during business hours (785-296-8605), sending an email request to bt@kdhe.state.ks.us, or through the CDC website at http://www.bt.cdc.gov/agent/smallpox/smallpox-images/index.asp.

Appendix II - Contact Information for State Agencies

Name	Phone Number	E-mail
EPIDEMIOLOGY HOTLINE (24/7)	**1-877-427-7317**	
BT Executive Director (Michael Moser, MD)	785, 296-1086	mmoser@kdhe.state.ks.us
BT medical director (Gianfranco Pezzino, MD)	785, 296-6179	gpezzino@kdhe.state.ks.us
BT program director (Mindee Reece)	785, 296-0201	mreece@kdhe.state.ks.us
Health Alert Network coordinator (Mary Rapp)	785, 296-6552	mrapp@kdhe.state.ks.us
National Pharmaceutical Stockpile coordinator (Sandy Johnson)	785, 291-3065	SJohnso1@Kdhe.state.ks.us
Risk communication specialist (vacant)	785, 368-8053	
Diagnostic Microbiology (Robert Flahart, Ph.D.)	785, 296-1636	rflahart@kdhe.state.ks.us
Virology (Patrick Hays, Ph.D.)	785, 368-8324	phays@kdhe.state.ks.us
Public Information Officer (Sharon Watson)	785, 296-5795	swatson@kdhe.state.ks.us
Hospital Bioterrorism Program Manager (Susan Morris)	785, 296-5201	samorris@kdhe.state.ks.us
Kansas Division of Emergency Management	785, 296-3176	
Kansas Division of Emergency Management, PAGER	785, 575-7370	7855757370@page.metrocall.com

Updated March 15, 2003

Annex III - Collection, handling and mailing of suspected smallpox specimens to the Virology Laboratory at KDHE to rule out varicella (chickenpox) or zoster (shingles)

Specimens from suspected chicken pox or shingles (VZV) cases should be obtained as early as possible after onset of lesions. The preferred specimen for viral isolation or direct detection by DFA is a swab of a fresh lesion. Appropriate specimens include vesicle fluid or swabbed lesion material obtained aseptically using throat swabs. Specimens from crusted lesions are of little or no diagnostic value, as isolation of varicella from specimens collected greater than 3 days past lesion onset is rare. For potential secondary contact cases, one should obtain a throat swab specimen as soon after onset of fever as possible.

Use a commercial viral transport system or one provided by DHEL for viral specimens (VTM) for storage and shipment of the samples. If no swab is included with the collection kit, you must use a sterile cotton or Dacron swab. After collection, put the swab into the transport tube or plastic sheath with both patient's name and date of collection identified and refrigerate it (do not freeze) if immediate mailing is not possible.

Unless special transportation by courier or other means is arranged, mail the specimen the day of collection or at latest the following day in a Styrofoam box containing a frozen gel pack and packing material to help insulate the specimen. Use Priority US Mail to assure that the specimen will arrive at DHEL the next day from most locations in Kansas. First-class mailing can take over 5 days. A delay in transport of greater than 2 days significantly reduces VZV identification by direct immunofluorescent assay (DFA) or by isolation in tissue culture due to loss of antigen stability and of the number of viable virus.

For any questions on collection and shipping please contact the Virology Laboratory staff at 785-296-1644 or Dr Patrick Hays at 785-368-8423. Call 1-877-427-7317 for all epidemiological inquiries.

INSTRUCTIONS:

· Follow bloodborne pathogen guidelines with disposable protective clothing (i.e., gloves, coat/gown, glasses/goggles) when collecting these specimens.

· Cut the tops off two pox lesions and place them into a sterile scewcap tube; tighten the cap and surround the tube with bubble-rap or paper towels.

· Scrape the base of two lesions with a sterile swab using a rotating motion.

· Use one side of the swab to make a smear on each of two clean glass slides with the lesion material, air dry the slides and then place them in a closable slide holder.

· Place the swab into a sterile tube; tighten the cap and then tape the cap. Place bubble-rap or paper towels around the tube.

(Alternatively a commercial dry VTM collection system can be used to produce the smear and viral isolation specimens)

· A 7 ml redtop (clot) blood tube should be drawn and placed in a double can single tube mailer and placed in the shipping container used for the other specimens.

· Place the slide holder and the two protected tubes in a Styrofoam box containing a precooled gel-pak and use packing material (i.e., paper towels) to reduce any specimen shifting during transport. Place a completed requisition form (patient and test request information) into a plastic zip bag and place on top of the specimens.

· Tape the box closed and label it with the clinical specimen types and the DHEL address

Updated: March 15, 2003